This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS OTTAWA 001675

SIPDIS

STATE FOR EB/IPC SWILSON; WHA/CAN PNORMAN; AND EB/DCT
USDOC FOR CBUSQUETS
DEPT PASS USTR FOR SCHANDLER AND CBURCKY
DEPT ALSO PASS FDA FOR MECKLES

E.O. 12958: N/A
TAGS: KIPR ECON CA
SUBJECT: CANADIAN PHARMACEUTICAL PATENTS: PARLIAMENTARY COMMITTEE POSTPONES DECISION TO AMEND REGULATIONS

¶1. Summary ) A Parliamentary committee has postponed a decision to recommend changes to Canada,s drug patent rules that cover the process for bringing generic drugs to the market once the innovator,s patents expire. The Canadian review mirrors the recent U.S. deliberations on the Hatch-Waxman law that led to a June 12 decision by the FDA to streamline the process for bringing generics to the market. The committee,s decision to delay a recommendation for possible regulatory change before the end of the current Parliamentary session is seen as a temporary victory for the brand-name pharmaceutical companies that oppose any legislative changes. End Summary.

¶2. After four days of testimony, the House Industry and Science committee postponed a decision to recommend reform of Canada,s drug patent rules until Parliament reconvenes in the fall. The committee reviewed the Patented Medicine Notice of Compliance (NOC) Regulations, which are also known as the &linkage regulations8 because these rules link the regulatory approval of a generic drug to the patent status of the drug it seeks to copy. A similar review of the Hatch-Waxman law in the U.S. led to the recent FDA decision, announced by President Bush on June 12, to institute new regulations to streamline the process for bringing generic drugs to the market.

¶3. The linkage regulations, which were last amended in 1998, block Health Canada from approving a generic drug for up to two years if there is any allegation of patent infringement. Generic companies complained that by filing sequential patents on minor improvements on a drug and then alleging infringement on each, brand-name companies can "evergreen8 the market for a drug long after its original 20-year patent expires. The generics proposed scrapping the automatic 24-month injunction altogether. The brand-name manufacturers encouraged the committee to maintain the status quo, arguing that the automatic injunction is necessary to prevent patent infringement and encourage the development of new drugs. Canada and the U.S. are the only countries that provide an automatic injunction in cases of alleged patent infringement.

¶4. The recent high profile review of the Canadian health care system by Roy Romanov, which was released last fall, recommended that the GOC consider overhauling the Notice of Compliance regulations. Health Canada, which administers the regulations, generally agreed with this recommendation, testifying to the committee that the growing complexity of patents has made it difficult for them to administer the NOC regulations. Industry Canada, on the other hand, argued against changes to the regulations, noting that they are necessary to protect and promote incremental innovation by brand-name companies. The Parliamentary committee was evenly divided on the issue and determined that they needed more information before deciding on whether or not to amend the regulations.

¶5. Comment ) Failure to reach a decision is a victory for the brand-name drug companies, who had hoped to avoid the Parliamentary review of the regulations altogether. With the upcoming Canadian elections it is not clear when or if the committee will reconvene to make a final decision on whether or not the regulations will be amended. Although Canada,s patent regime is generally considered more pro-generic than the U.S. system, even after the recent decision by the FDA, the perception that the U.S. is taking action to &lower the costs8 of prescription medications could motivate the committee to recommend changes to the linkage regulations.
CELLUCCI